

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1684V

UNPUBLISHED

FRANK COLUCCIO,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: February 9, 2022

Special Processing Unit (SPU);
Entitlement to Compensation; Ruling
on the Record; Findings of Fact;
Onset; Influenza (Flu) Vaccine;
Shoulder Injury Related to Vaccine
Administration (SIRVA)

Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for petitioner.

Sarah Black Rifkin, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT AND RULING ON ENTITLEMENT¹

On October 30, 2019, Frank Coluccio filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that he suffered a shoulder injury related to vaccine administration (“SIRVA”) caused by an influenza (“flu”) vaccine administered on October 22, 2018. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that there is a preponderance of evidence that the onset of Petitioner's injury (specifically shoulder pain) occurred within 48 hours of his vaccination. I otherwise find that Petitioner is entitled to compensation for a right SIRVA.

I. Relevant Procedural History

This case was initiated on October 30, 2019. Initially, Respondent indicated a willingness to engage in settlement discussions, but the parties reached an impasse. On May 24, 2021, Respondent filed a Rule 4(c) Report. ECF No. 30, Respondent's Rule 4(c) Report ("Report"). Respondent opposed compensation, arguing in part that Petitioner failed to establish a Table claim because the records did not established onset of his injury within 48 hours of Petitioner's vaccination. Report. at 4-5.

Petitioner filed a Motion for a Ruling on the Record on July 16, 2021, in support of his claim. Petitioner's Motion for Ruling on the Record Regarding Onset ("Mot."), ECF No. 33. Respondent filed a response on July 30, 2021. Respondent's Response to Petitioner's Motion for a Ruling on the Record ("Resp."), ECF No. 34. Petitioner filed a reply on August 6, 2021. Petitioner's Reply Brief ("Reply"), ECF No. 36. This matter is now ripe for resolution.

II. Petitioner's Medical Records

Mr. Coluccio received a flu vaccine on October 22, 2018 in his right shoulder. Ex. 2 at 1. Twenty-seven days later on November 18, 2018, Petitioner presented to an urgent care center complaining of right shoulder pain for "3 weeks". Ex. 3 at 8. Petitioner stated that his symptoms "occurred after the flu shot". Ex. 3 at 8. Upon exam, he exhibited a decreased range of motion and was prescribed ibuprofen and Tylenol for pain control. *Id.* at 9.

Petitioner saw his primary care physician, Dr. Ruden, on November 20, 2018. Ex. 4 at 89-90. Petitioner was assessed with "Tendonitis from flu[shot]." *Id.* at 89.³

Petitioner was next seen on December 7, 2018. Ex. 4 at 91. At that time, he complained of arm pain and numbness for over two months with no history of trauma and "Pain after flu vax...". *Id.*⁴ Petitioner exhibited a reduced range of motion with weakness

³ The records state that Petitioner's diagnoses includes "Shoulder impingement syndrome, left/ Adhesive capsulitis, R/o RTC tear...."

⁴ There is also a reference to left-sided arm pain, which appears to be an error because only Petitioner's right shoulder was examined. See ex. 4 at 93.

in his right shoulder along with signs of impingement. Ex. 4 at 93-94. He was diagnosed with impingement syndrome and adhesive capsulitis. *Id.* at 97. An MRI revealed tendinosis, tendinitis, and mild to moderate bursitis in his right shoulder. Ex. 5 at 4-5.

Petitioner had a follow-up appointment on December 14, 2018. He reported a history of right shoulder pain “after flu vax”. Ex. 4 at 99. Upon examination, Petitioner exhibited reduced strength and reduced range of motion. *Id.* at 101-102. He was assessed with impingement, syndrome, adhesive capsulitis, and calcific bursitis. *Id.* 99-106. He also received a cortisone injection at that time. *Id.* at 106.

Between January 1, 2019 and March 22, 2019 Petitioner attended 19 physical therapy sessions. Ex. 6. At his initial evaluation, he reported right shoulder pain following a flu shot on October 22, 2018. Ex. 6 at 4. Petitioner reported “pain in his shoulder the following day which he attributed to soreness but ... note[d] the pain ha[d] gotten progressively worse over the past few months.” *Id.* Additionally, “flu shot” was listed as the mechanism of onset. *Id.*

Petitioner continued to complain of right shoulder pain at follow-up appointments with his primary care physician on January 22, 2018 and March 22, 2019. Ex. 4 at 107, 111. He presented to an orthopedist, Dr. Catalano, on April 23, 2019 for continued shoulder pain, stating that “he had a flu shot on 10/22/2018, 7 days after [he] felt great pain with numbness in the right hand.” Ex. 7 at 2. Petitioner was assessed with right shoulder capsulitis and ulnar nerve palsy of the right upper extremity. *Id.* at 4. A follow-up with Dr. Catalano on June 7, 2019 indicated that Petitioner’s right shoulder was improving, but that he still experienced pain. *Id.* at 5-6.

III. Affidavit Evidence

Mr. Coluccio submitted two declarations in support of his petition. Exs. 1, 11. In the first, he stated that he received a flu shot on October 22, 2018 and “had some pain” but was not “immediately concerned. Ex. 1 at 1. However, by the next day his pain increased and gradually worsened “over the next several weeks. *Id.* Petitioner reiterated in his supplemental declaration that he initially felt pain in his right shoulder following his flu shot, and it gradually worsened over the following weeks. Ex. 11 at 1-2. Petitioner also stated that, when he spoke with medical providers, he did his best to “estimate how much time had passed” since he received the flu shot, and that his symptoms started within a day of the vaccine and worsened significantly “about one week later.” *Id.* at 2.

Mr. John Winter, Petitioner’s domestic partner, submitted a declaration in this matter. Ex. 10. He stated that he also received a vaccine on October 22, 2018 and had

some initial discomfort. However, where his shoulder pain resolved within 24-36 hours, Mr. Winter stated that Petitioner continued to report pain that gradually worsened. *Id.* at 1-2.

Amy Winter, John Winter's daughter, and Allison Coluccio, Petitioner's niece, also submitted declarations in this matter adding additional corroborating statements. Ex. 12, 13.

IV. Parties' Arguments

Respondent argues that Petitioner has failed to show onset of his pain occurred within 48 hours of his vaccination. Report at 4. Respondent notes that Petitioner's medical records do not establish a definite date of onset for his symptoms, and otherwise employ vague phrases that make it difficult to determine whether his pain likely began within 48 hours after his vaccine. *Id.* at 4-5, Reply at 2-3.

Petitioner argues that the evidence establishes onset of his injury within 48 hours of his vaccination. Mot. at 3. Petitioner also argues that there is preponderant evidence that he suffered a SIRVA injury, and in the alternative that his injury was caused in fact by the October 22, 2018 flu vaccine. Reply at 7-8.

V. Fact Findings and Ruling on Entitlement

At issue is whether Petitioner meets the requirements for a SIRVA as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI"). Specifically, the parties dispute whether Petitioner's symptoms (specifically pain) occurred within 48 hours. 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,⁵ a petitioner must establish that he suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he received. Section 11(c)(1)(C).

⁵ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for his injury. See § 11(c)(1)(A)(B)(D)(E).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

The United States Court of Federal Claims has also recognized that “medical records may be incomplete or inaccurate.” *Camery v. Sec’y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

Medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

A. Factual Findings Regarding QAI Criteria for Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence supports each of the QAI requirements for a Table SIRVA.

1. Petitioner has no Prior Right Shoulder Condition or Injury

The first requirement under the QAls for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent has not contested that Petitioner meets this criterion, and I find that he has demonstrated a lack of history of pain, inflammation, or dysfunction of his right shoulder that would explain his symptoms. See Ex. 4 at 69-85 (records from the period prior to Petitioner's vaccination that include no history of prior shoulder pain).

2. Onset of Petitioner's Injury was within Forty-eight Hours of his Flu Vaccination

Preponderant evidence supports the conclusion that onset of Petitioner's injury was within 48 hours of vaccination. The following finding of fact is based on a complete review of the record, including all medical records, declarations, and additional evidence filed. Specifically, I highlight the following:

- Petitioner received a flu vaccine in his right shoulder on October 22, 2018. Ex. 2 at 1.
- On November 18, 2018, Petitioner complained of right shoulder pain that "occurred after the flu shot." Ex. 3 at 8. The records indicate that Petitioner affirmatively linked his shoulder pain to the flu vaccine at this time.
- Petitioner complained of continued shoulder pain on December 7, 2018. Ex. 4 at 91. The record reports Petitioner had arm pain for over two months with no history of trauma. The record again links Petitioner's pain to his flu vaccine, stating "pain after flu vax". *Id.* at 91.
- Petitioner reported continued right shoulder pain on December 14, 2018. Ex. 4 at 99. The record states pain "after flu vax". *Id.*
- At the initial physical therapy evaluation, Petitioner reported right shoulder pain following a flu shot on October 22, 2018. Ex. 6 at 4. Petitioner reported "pain in his shoulder the following day which he attributed to soreness but ... note[d] the pain ha[d] gotten progressively worse over the past few months." *Id.* Additionally, "flu shot" was listed as the mechanism of onset. *Id.*

Based on the above, Table onset is evidentiarily established. Even if the initial record evidence of Petitioner's first complaint of shoulder pain is a bit vague, it is not

inconsistent with his contentions, and his witness statement is also reasonably taken into account. All other records thereafter consistently identify onset as immediately after vaccination and repeatedly link his pain to the flu vaccine.

Further, Petitioner acknowledged that the initial record evidence may be vague because he did his best to estimate how much time passed since his pain started. Ex. 11 at 1-2. He also stated that his pain occurred within a day of receiving the vaccine, and gradually worsened thereafter. Ex. 1 at 1, Ex. 11 at 1-2. The declaration evidence submitted in this matter provide additional corroborating evidence. See, e.g., Exs. 10 at 1-2, 12, 13.

3. Petitioner's Pain was Limited to his Right Shoulder

The third requirement under the QAIs for a Table SIRVA is that Petitioner's pain and recued range of motion is limited to the shoulder in which he received a vaccine. 42 C.F.R. § 100.3(c)(10)(iii). Respondent has not contested that Petitioner meets this criterion, and I find that he has demonstrated pain and reduced range of motion only in his right shoulder. See Ex. 4 at 91, 95 (reporting only right shoulder pain and reduced range of motion since he received his flu shot).

4. There is No Evidence of Another Condition or Abnormality

The last QAI criteria for a Table SIRVA states that there must be no other condition or abnormality which would explain petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent has not contested that Petitioner meets this criterion, and there is no evidence in the record to the contrary. Thus, the record contains preponderant evidence establishing that there is no other condition or abnormality which would explain the symptoms of Petitioner's right shoulder injury.

B. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received flu vaccine intramuscularly in his right shoulder on October 22, 2018, in New York, NY. Ex. 2 at 1; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for his injury. Ex. 1 at 2; Section 11(c)(1)(E) (lack of prior civil award).

As stated above, I have found that the onset of Petitioner's right shoulder pain was within 48 hours of vaccination. See 42 C.F.R. § 100.3(c)(10)(ii) (setting forth this QAI requirement). This finding also satisfies the requirement that Petitioner's first symptom or manifestation of onset occur within the time frame listed on the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(XIV)(B) (listing a time frame of 48 hours for a Table SIRVA following receipt of the influenza vaccine). Therefore, Petitioner has satisfied all requirements for a Table SIRVA.

The last criteria which must be satisfied by Petitioner involves the severity of his SIRVA. For compensation to be awarded, the Vaccine Act requires that a petitioner suffer the residual effects of his right shoulder injury for more than six months or that his condition resulted in inpatient surgical intervention. See Section 11(c)(1)(D)(i), (iii) (statutory severity requirement). The records demonstrate, and Respondent does not contest, that Petitioner suffered the residual effects of his shoulder injury for more than six months. See, *e.g.*, Ex. 7 at 5-6. Thus, this requirement is also met.

Based upon all of the above, Petitioner has established that he suffered a Table SIRVA. Additionally, he has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

VI. Conclusion

In view of the evidence of record, I find that there is preponderant evidence that the onset of Petitioner's injury, specifically shoulder pain, was within 48 hours of his vaccine. Further, based on the evidence of record, I find that Petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master